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EX

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/743,892 | 12/22/2003 | Samy Ashkar | CMCC 512 DIV | 2155 |
| 23579 | 7590 | 10/14/2005 | EXAMINER | |
| | | | LUKTON, DAVID | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |
| DATE MAILED: 10/14/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/743,892 | ASHKAR, SAMY | |
| | Examiner | Art Unit | |
| | David Lukton | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 August 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15,18,21,22,26,29-31 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 21,22,26,29-31 and 34 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 15 and 18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

Pursuant to the directives of the response filed 8/8/05, claims 15, 21, 22, 26 29 have been amended.

Claims 15, 18, 21, 22, 26, 29-31, 34 remain pending. Claims 21, 22, 26, 29-31, 34 remain withdrawn from consideration.

Applicants' arguments filed 8/8/05 have been considered and found not persuasive.

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The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 15 and 18 are rejected under 35 U.S.C. §103 as being unpatentable over Reich (USP 5124155) in view of Kiefer (*Nucleic Acids Res* 17, 3306, 1989) or Pierschbacher (USP 5,880,092) in view of Kiefer (*Nucleic Acids Res* 17, 3306, 1989).

As indicated previously, Reich and Kiefer both teach that RGD-containing peptides are effective to promote wound healing. Neither of these references, however, disclose that RGD is an “osteopontin-derived” peptide. Kiefer provides the amino acid sequence of osteopontin. As is evident, this peptide contains the subsequence RGD. Accordingly, RGD is an “osteopontin-derived” peptide.

In response to the foregoing, applicants have argued that taken together, the references teach that full length osteopontin promotes cell adhesion. However, the basis of this assertion is not evident, and applicants have not explained it. The fact is that the cited references do not disclose any activity for full length osteopontin, whether the activity is relevant to the claimed invention or not.

The issue is that the term “osteopontin-derived peptide” is nebulous and subject to broad interpretation. This term could mean that one simply takes any dipeptide or tripeptide subsequence that is present in osteopontin, and then proceeds to add any number of amino acids to the N-terminus or C-terminus. There is possibly the implied limitation that the total number of amino acids present in the resulting peptide must be less than the total number which is present

in osteopontin itself, but other than that, there are no limitations. Applicants have argued that the limitations recited on page 5, line 10+ are implicitly incorporated into the claims. First, this is not necessarily true, but even if it is, the rejection is still on firm ground. Consider the passage in question:

In accordance with this invention, an "osteopontin derived chemotactic peptide" is a peptide derived from osteopontin having chemotactic activity. Peptides of this invention include peptides comprising no more than about 60 amino acid residues and comprising at least approximately five amino acid residues in length, and preferably at least about 6-45 amino acid residues in length, and more preferably at least about 10-35 amino acid residues in length, from the C-terminal region of the osteopontin polypeptide.

First, note the following passage:

"an 'osteopontin derived chemotactic peptide' is a peptide derived from osteopontin having chemotactic activity".

As it happens, the peptides disclosed in Reich ('155) and Pierschbacher ('092) qualify as "osteopontin derived" peptides; the secondary reference merely provides evidence of this.

The examiner does take note of the following on page 5 of the specification:
"Peptides of this invention include peptides comprising..."
This phrase is then followed by various possible limitations. The first point is that this phrase is not actually present in the claims, and so the claims can be interpreted broadly. But even if applicants were to insert the above phrase into the claims, it would still not have the effect of imposing any limitations on the

sequence or composition of the peptides; this conclusion is reached because of the term "include". This is an open-ended term, which has the effect of not excluding other embodiments.

Thus, for each of a few reasons, it remains the case that this rejection is justified.

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Claims 15 and 18 are rejected under 35 U.S.C. §103 as being unpatentable over Carney (USP 6,630,572) in view of Kiefer (*Nucleic Acids Res* 17, 3306, 1989).

As indicated previously, Carney discloses that peptides containing the RGD subsequence are effective to promote wound healing. See, for example, claims 1-16 of the patent. Carney does not disclose that RGD is an "osteopontin-derived" peptide. Kiefer provides the amino acid sequence of osteopontin. As is evident, this peptide contains the subsequence RGD. Accordingly, RGD is an "osteopontin-derived" peptide.

The examiner's arguments are the same as those given above

The rejection is maintained.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800